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Drug News

New Drug Approval Updates 2000

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- **Protonix (pantoprazole sodium)**

New Oral Medication for Type 2 Diabetes Approved

December 22, 2000

ST. LOUIS (MD Consult) - The FDA last month announced its approval of nateglinide, a D-phenylalanine derivative, as the first of a new class of medications to control glycemia in type 2 diabetes. The new product will be marketed by Novartis Pharmaceuticals Corp. as Starlix.

Nateglinide is indicated for use in patients with type 2 diabetes whose hyperglycemia is not adequately controlled by diet and exercise. It may be used as monotherapy or in combination with metformin.

Nateglinide acts to stimulate rapid, short-acting insulin secretion. In so doing, the drug reduces postprandial hyperglycemia while improving overall glucose control, as measured by glycosylated hemoglobin level. The recommended dosage of nateglinide, alone or with metformin, is 120 mg three times daily before meals.

In clinical trials, nateglinide was efficacious in reducing mealtime glucose spikes and glycosylated hemoglobin levels over a 24-week treatment period. Even greater improvements in glucose control were achieved through the complementary action of nateglinide and metformin. Nateglinide was safe and well-tolerated. The major adverse effect was a 2.4% rate of hypoglycemia, although just 0.3% of patients had to discontinue treatment for this reason.

By avoiding episodes of postprandial hyperglycemia and maintaining consistent blood glucose control, the new medication is expected to reduce the risk of long-term organ damage in patients with type 2 diabetes.

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CellCept Approved by FDA for use in Children Undergoing Renal Transplantation

December 20, 2000

ST. LOUIS (MD Consult) - On December 20th, the U.S. Food and Drug Administration (FDA) granted marketing approval for Hoffman-La Roche's CellCept (mycophenolate mofetil) for the prevention of acute rejection in pediatric renal transplant patients.

The organ transplant therapy was approved in three oral formulations including a 250mg capsule, a 500mg capsule, and an oral solution with a strength of 200mg/mL.

According to the FDA, the drug was first approved in May 1995 for prophylaxis of organ rejection in adults receiving allogenic renal transplants. In addition, CellCept was approved in February 1998 for prophylaxis of organ rejection in patients receiving heart transplants.

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Angiomax Receives FDA approval for use in Angioplasty as a Heparin Alternative

December 18, 2000

ST. LOUIS (MD Consult) - The Medicines Company announced in a press release on December 18th that Angiomax (bivalirudin) has been approved by the U.S. Food and Drug Administration (FDA). Angiomax, a thrombin-specific anticoagulant, is indicated for use in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). It is intended for use with aspirin and has only been studied in patients receiving concomitant aspirin therapy.

FDA approval of Angiomax was based on data from double-blinded clinical trials. A patient group of 4,312 that underwent PTCA for either new onset angina, accelerating episodes of angina, or angina at rest were studied. The results were compared with heparin - the current standard used for anticoagulation during PTCA. The clinical data demonstrated a 22% reduction in the risk of death, myocardial infarction (MI), or revascularization for Angiomax-treated patients (6.2%) as compared with patients treated with heparin (7.9%). This difference was sustained at both 90 days and 6 months.

The same study also showed a 62% decrease in the incidence of major hemorrhage for Angiomax-treated patients (3.5%) as compared to heparin-treated patients (9.3%). The company notes that these results translated into 68 fewer patients who experienced adverse outcomes for every 1,000 patients that were treated.

According to the company, Angiomax is contraindicated in patients with active major bleeding or hypersensitivity to Angiomax or its components. It is not intended for intramuscular use and, although most bleeding associated with the use of Angiomax during PTCA occurs at the arterial puncture site, hemorrhage may occur at any site. The most common non-bleeding side effects of Angiomax includes back pain, pain, nausea, headache, and hypotension.

The company also reports that the safety and effectiveness of Angiomax has not been established in patients with unstable angina who are not undergoing PTCA or in patients with other acute coronary syndromes. In addition, the drugs safety and effectiveness have not been established when used in conjunction with platelet inhibitors other than aspirin.

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Flavored Orapred Receives FDA Approval for Treatment of Pediatric Asthma

December 15, 2000

ST. LOUIS (MD Consult) - In a press release from December 15th, Ascent Pediatrics Inc. announced that the U.S. Food and Drug Administration (FDA) has granted approval to market Orapred (prednisolone sodium phosphate 20.2mg/5mL, equivalent to prednisolone 15mg/5mL) as a treatment for children with asthma and other inflammatory conditions.

Orapred, a liquid corticosteroid, has a "pleasant grape flavor." The company notes that improved taste may make it easier for children to tolerate.

"Currently available liquid corticosteroids have a very bitter and objectionable taste. Through its proprietary taste-making technology, Orapred offers pediatricians the liquid steroid strength they prefer and the taste children prefer," said Emmett Clemente, Ph.D., president and chairman of Ascent Pediatrics.

According to the company, Orapred is not recommended for persons with systemic infections and its potential side effects include dermatologic and gastrointestinal disturbances.

Orapred is available by prescription only.

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FDA Advisers Back Approval of Femara as First-line Therapy for Metastatic Breast Cancer Therapy

December 13, 2000

ST. LOUIS (MD Consult) - Novartis Oncology announced on December 13th that the U.S. Food and Drug Administration's Oncologic Drugs Advisory Committee recommended approval of Femara (letrozole tablets) as a first-line treatment for advanced breast cancer in postmenopausal women.

The advisory committees recommendation is based on results of a study involving more than 900 postmenopausal women who had locally advanced (stage IIIB) disease, metastatic breast cancer, or a recurrence of cancer not treatable with either surgery or radiotherapy. The study was a head-to-head, randomized, double-blind, multi-center trial comparing the use of Femara and tamoxifen. Tamoxifen is the current standard of therapy for advanced breast cancer.

The study found that Femara delays progression of advanced breast cancer for 9.4 months versus 6.0 months for tamoxifen. The results also showed significant differences in overall tumor response rates (30% vs. 20%), clinical benefit (49% vs. 38%), and time to treatment failure (9.1 months vs. 5.7 months). In a related study, Femara and tamoxifen were given to postmenopausal women as a pre-operative treatment to reduce tumor size prior to surgery. After four months of preoperative therapy, clinical responses were significantly better for Femara than tamoxifen (55% vs. 36%).

Femara was originally approved in 1997 for its current indication, treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Femara is a once-a-day oral treatment.

Femara is contraindicated in patients with known hypersensitivity to Femara or any of its excipients. The most common adverse effects reported include musculoskeletal pain (21%), nausea (13%), headache (9%), joint pain (8%), fatigue (8%), vomiting (7%), or dyspnea (7%).

"The availability of letrozole as a first-line option could lead us to seriously consider changing the treatment paradigm for advanced breast cancer in postmenopausal women," said Dr. Matthew Ellis, Clinical Director of Duke University's Breast Cancer program and Femara investigator.

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Trizivir Wins FDA Approval and may Simplify Therapy for HIV Patients

November 15, 2000

ST. LOUIS (MD Consult) - Trizivir, a new product that combines three anti-HIV medicines into a single tablet, has been approved by the U.S. Food and Drug Administration.

Trizivir tablets combine two widely used HIV medications, Epivir (lamivudine; 3TC) and Retrovir (zidovudine; AZT), along with Ziagen (abacavir sulfate). It is the first product to combine three antiretroviral drugs into a single tablet. Trizivir can be taken as one tablet in the morning and one tablet in the evening without regard to food or water intake.

According to a recent press release from the drug manufacturer, Glaxo Wellcome, Trizivir is indicated alone or in combination with other antiretroviral agents for the treatment of HIV infection. It is intended only for patients whose regimen would otherwise include abacavir, lamivudine, and zidovudine. Because it is a fixed-dose tablet, Trizivir should not be prescribed for adults or adolescents who weigh less than 40 kilograms (approximately 88 pounds) or other patients requiring dose adjustment (such as those with impaired renal function or experiencing dose-limiting side effects). Trizivir must not be used by patients who have previously experienced a hypersensitivity reaction to abacavir, which is a medicine in Trizivir and Ziagen.

The press release also strongly warns that the most serious adverse event associated with abacavir (a medicine in Trizivir and Ziagen) is a hypersensitivity reaction that can be life threatening and has been fatal in some cases. It is characterized by fever, skin rash, fatigue, and gastrointestinal symptoms (such as nausea, vomiting, diarrhea, or abdominal pain). Respiratory symptoms such as dyspnea, pharyngitis, or cough may also occur. In clinical studies, hypersensitivity reaction has been observed in approximately 5 percent of patients. The diagnosis of hypersensitivity reaction should be carefully considered for patients presenting with symptoms of acute respiratory diseases, even if alternative respiratory diagnoses (pneumonia, bronchitis, flu-like illness) are possible. Patients and health care professionals should also watch for respiratory symptoms such as shortness of breath, sore throat, or cough.

To avoid a delay in diagnosis and minimize the risk of a life-threatening hypersensitivity reaction, Glaxo Wellcome also states that Trizivir should be permanently discontinued if hypersensitivity cannot be ruled out, even when other diagnoses are possible. Rechallenge is contraindicated after a diagnosis of hypersensitivity. Symptoms of this reaction usually occur within the first six weeks of treatment although these reactions may occur at any time during therapy. The symptoms of this reaction get progressively worse with continued treatment with abacavir (Trizivir or Ziagen), but generally resolve following permanent discontinuation of Trizivir or Ziagen. Patients experiencing these symptoms should stop taking Trizivir or Ziagen and contact a physician immediately. Patients experiencing this reaction must not take Trizivir or Ziagen again; restarting the drug after a hypersensitivity reaction has resulted in cases of life-threatening and fatal reactions. When therapy with Trizivir or Ziagen has been discontinued and reinitiation of therapy is under consideration, the reason for discontinuation should be evaluated to ensure that the patient did not have a hypersensitivity reaction. A Medication Guide and Warning Card for Trizivir or Ziagen must be provided by the pharmacist to the patient with each new and refill prescription in order to provide further information to the patient on this drug. A person who has taken Ziagen and experienced a hypersensitivity reaction must not take Trizivir or Ziagen.

In clinical trials when Ziagen was taken, primarily with Epivir and Retrovir (the components of Trizivir), the most commonly reported adverse events were nausea (47%), nausea and vomiting (16%), diarrhea (12%), loss of appetite/anorexia (11%), and insomnia/other sleep disorders (7%). Zidovudine, one of the three active ingredients in Trizivir, has been associated with hematologic toxicity including neutropenia and severe anemia, particularly in patients with advanced HIV disease. Prolonged use of zidovudine has been associated with symptomatic myopathy. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including abacavir, zidovudine, lamivudine, and other antiretrovirals. The individual components of Trizivir will continue to be available as Combivir, Epivir, Retrovir and Ziagen in their existing formulations.

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Lunelle, a Once-Monthly Injectable Contraceptive Approved

October 10, 2000

ST. LOUIS, (MD Consult) - The FDA announced this October that it has approved a combination of medroxyprogesterone acetate and estradiol cypionate for use as a once-monthly injectable contraceptive. The new product, developed by Pharmacia Corp., will be marketed as Lunelle.

Lunelle is viewed as a practical alternative to daily oral contraceptives. It is to be given once monthly by intramuscular injection. The recommended dosing interval is 28 to 30 days, and no longer than 33 days. The initial injection should be given within 5 days after a normal menstrual period, to ensure that the patient is not pregnant.

In clinical trials, the 12-month failure rate of Lunelle was less than 1%. A key advantage of Lunelle is prompt reversibility. Fertility returns within 2 to 4 months after the patient stops receiving injections, more quickly than with the injectable contraceptive Depo-Provera (medroxyprogesterone).

The manufacturer believes that Lunelle will offer a convenient alternative to oral contraceptive pills. Compliance may be enhanced because patients won't need to remember to take a pill every day. Women in the clinical trials did not mind having to go to the doctor's office every month to receive injections, and in fact enjoyed the regular contact with health care providers.

The risks and side effects of Lunelle are comparable to those of other hormonal contraceptives. Altered bleeding patterns and weight gain are possible. Users should be urged not to smoke, and advised that Lunelle will not protect against HIV or other sexually transmitted diseases.

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Mifepristone Approved for Termination of Early Pregnancy

September 29, 2000

ST. LOUIS (MD Consult) - The FDA has announced the approval of the oral drug mifepristone for termination of early pregnancy. The approval is accompanied by significant prescribing restrictions.

The drug will be marketed as Mifeprex by Danco Laboratories. Mifepristone is approved for use within 49 days or less from the beginning of the woman's last menstrual period. The drug will be distributed only through physicians' offices and clinics, and prescribing physicians must meet certain qualifications in terms of diagnostic and follow-up services.

Mifepristone is given in an initial dose of 600 mg, or three 200 mg pills. This is followed 2 days later by 400 µg of misopristol. A 14-day follow-up examination is made to confirm termination of pregnancy.

Prescribing physicians must sign a statement certifying that they have read the prescribing information, that they can accurately determine the duration of pregnancy and detect ectopic pregnancies, and that they can provide or arrange for surgical abortion in case of incomplete abortion or severe bleeding.

In addition, all patients receiving mifepristone must receive a Medication Guide covering how to use the drug, who should not take it, and the possible side effects.

Approval was based on U.S. and French clinical trials. Mifepristone has been used in Europe for years, with effectiveness rates of 92% to 95%.

Bleeding and cramping are expected effects; nausea, headache, and vomiting may occur as well. About 1% of patients taking mifepristone will require surgery to stop heavy bleeding. The drug should not be used in women with ectopic pregnancies, intrauterine devices, chronic adrenal gland failure, current corticosteroid therapy, allergy to mifepristone or misoprostol, or bleeding disorders.

The political controversy surrounding approval of mifepristone, sometimes called RU-486, has been extensively covered in the popular media. The product is sponsored by the nonprofit Population Council, which plans extensive postmarketing studies.

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FDA Approves Trisenox as Second-Line Therapy for Leukemia

September 29, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has approved Trisenox (arsenic trioxide; manufactured by Cell Therapeutics) as a second-line therapy for patients with promyelocytic leukemia (APL). Trisenox is indicated for patients who do not respond to trans-retinoic acid and anthracycline-based chemotherapy, or who suffer a relapse after using these therapies.

Trisenox works by converting immature cancerous white blood cells into normal white blood cells. However, because abnormal white blood cell counts in APL are already high, the use of arsenic trioxide can lead to a potentially fatal syndrome called APL differentiation syndrome. This condition is characterized by inflammation and fluid accumulation that particularly targets the linings of the heart and lungs. Patients who develop this syndrome should immediately stop leukemia therapy and be given high-dose steroids.

Approval for Trisenox was based on a clinical study of 40 patients with refractory or relapsed APL. More than two thirds (28, or 70%) achieved disease remission after a median of 51 days of Trisenox therapy. Of note, of the 8 patients who developed APL differentiation syndrome, none required suspension of therapy.

Other side effects associated with Trisenox include prolongation of the Q-T interval, abdominal discomfort, nausea and vomiting, headache, fatigue, skin changes, and fluid accumulation.

The approval of Trisenox offers another option for patients with APL who are refractory to or experience recurrence after first-line chemotherapeutic regimens (about 400 new patients each year).

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FDA Approves QVAR as the First CFC-free Corticosteroid Aerosol Inhaler for Treating Asthma

September 19, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has granted approval to QVAR (beclomethasone dipropionate [BDP] with a hydrofluoroalkane [HFA] propellant; manufactured by 3M Pharmaceuticals) for the long-term treatment of asthma in adults and children at least 12 years old. QVAR becomes the first metered dose inhaler for long-term asthma treatment that is free of chlorofluorocarbons (CFCs). Its approval reflects the goal of the FDA and other international health organizations to phase out the use of CFC-containing products because of their link to ozone damage.

BDP exerts its effect by treating the inflammatory component of asthma. The QVAR metered-dose inhaler delivers BDP in smaller-size particles, which are more able to reach the less-accessible small airways of the lungs. Thus, the BDP is more effective, and a lower dose can be used to achieve the same effectiveness as other

therapies. Clinical trials comparing QVAR with a CFC-based BDP inhaler have shown that QVAR delivers about 50% more of each dose of BDP to the lungs, and less to the throat.

QVAR joins another CFC-free inhaler, Proventil (manufactured by Schering), that is used for the short-term relief of asthma attacks. Both drugs will be useful for treating the approximately 17 million Americans who have asthma, many of whom are children.

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FDA Approves Kaletra as an Antiretroviral Treatment for Human Immunodeficiency Virus Infection

September 15, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has granted accelerated approval to Kaletra (lopinavir/ritonavir, formerly known as ABT-378/r; manufactured by Abbott Laboratories) as treatment for human immunodeficiency virus (HIV) infection. This antiretroviral medication can be combined with other antiretroviral medications, and it can be used both in patients with prior HIV treatment and those naïve to treatment. The drug can be used in adults, and it is the only protease inhibitor approved for use in children as young as six months old.

Accelerated approval for Kaletra is based on a 24-week controlled Phase III trial, and on other open-label, 72-week trials to evaluate different doses of the drug. The Phase III trial involved 635 patients with HIV who were naive to antiretroviral therapy. Intent-to-treat analysis indicated that the combination of Kaletra, stavudine, and lamivudine was significantly more effective in reducing HIV RNA levels to below detectable levels than was the combination of nelfinavir, stavudine, and lamivudine (reductions in 79% of patients, vs 70%, respectively). Among the patients who remained on treatment, the reductions in viral loads with the Kaletra and the nelfinavir combinations were even greater (reduction in 92% of patients, vs 81%, respectively).

The most common side effects of Kaletra (noted in 2% of patients in the Phase III trial) consist of abdominal pain, abnormal stools, diarrhea, fatigue and/or weakness, headache, nausea, and vomiting. Other adverse effects include increases in triglyceride and cholesterol levels, pancreatitis, and abnormalities in liver function. Protease inhibitor therapy has been associated with changes in body fat, increased bleeding in patients with hemophilia, and diabetes and high blood sugar. It is not known whether Kaletra will halt the progression of HIV. However, the drug does not prevent the acquisition of illnesses associated with advanced HIV infection, such as opportunistic infection.

Kaletra is available as capsules and as a liquid formulation. In adults, the drug is taken with food twice a day. In children 6 months to 12 years old, dosages are based on body weight. Although pharmacies should refrigerate Kaletra until dispensed, patients do not need to refrigerate the drug if it is used within 2 months.

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FDA Approves Atacand as Second-line Therapy for Hypertension

September 7, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has approved Atacand HCT (candesartan cilexetil + hydrochlorothiazide; manufactured by AstraZeneca) as a second-line therapy for hypertension. This fixed-dose combination drug controls blood pressure in patients whose condition cannot be controlled by single therapy alone.

Atacand HCT combines the effects of angiotensin II receptor blockers (which inhibit the effects of angiotensin II on constricting blood vessels) with those of diuretics (which improve the elimination of salt and fluid from the body).

Approval for Atacand HCT is based on 12 clinical studies involving 4,600 patients with hypertension who were given candesartan and hydrochlorothiazide in combinations of 32 mg and 12.5 mg or 16 mg and 12.5 mg. Both formulations were well tolerated and induced reductions in systolic blood pressure of 14-18 mm Hg and diastolic blood pressure of 8-11 mm Hg. Furthermore, these reductions were maintained for at least 24 hours.

The most common side effects of Atacand HCT are upper respiratory infection, dizziness, back pain, and flu-like symptoms. The drug is contraindicated in pregnancy, and women who become pregnant while taking the drug should discontinue its use.

Atacand HCT will be marketed in both formulations tested (32 mg/12.5 mg or 16 mg/12.5 mg). The drug offers another option for the 50 million Americans who have hypertension.

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FDA Approves Arimidex as First-line Therapy for Advanced Breast Cancer

September 6, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has approved Arimidex (anastrozole; manufactured by AstraZeneca) as first-line treatment for advanced breast cancer in postmenopausal women. Previously, the drug had been approved for use only in women who did not respond to tamoxifen. Thus Arimidex becomes the first aromatase inhibitor to gain FDA approval as first-line therapy for advanced breast cancer.

Arimidex works by inhibiting estrogen production by the adrenal glands, thus reducing circulating estrogen levels. In contrast, tamoxifen (anti-estrogen class of drug) works by inhibiting the use of estrogen by the cancer cell.

The new indication for the drug is based on two trials in North America and Europe comparing Arimidex and tamoxifen. Both trials found the two drugs to be similar in their efficacy and tolerance when prescribed at the time of diagnosis. The European trial found that Arimidex was particularly effective in women with estrogen receptor-positive advanced breast cancer.

To advise physicians of this new indication for Arimidex, AstraZeneca says it plans to provide breast cancer specialists and oncologists with patient educational materials within the next few weeks. The new approval offers another option for the 10,500-plus women who are diagnosed with advanced breast cancer each year.

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FDA Approves Advair Diskus as Therapy for Asthma

August 28, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has approved Advair Diskus (fluticasone propionate + salmeterol inhalation powder; manufactured by Glaxo Wellcome) as the first medication to treat both underlying components of asthma: inflammation and bronchoconstriction. Clinical trials have shown that treating both components of asthma provides greater asthma control than treating either component alone at the same doses.

The Advair Diskus inhaler contains both a corticosteroid (which reduces swelling and irritation of the airways) and an inhaled long-acting bronchodilator (which helps prevent tightening of the muscles surrounding the airways). Three formulations will be available: Advair Diskus 100/50 (100 g fluticasone, 50 g salmeterol), Advair Diskus 250/50 (250 g fluticasone, 50 g salmeterol), and Advair Diskus 500/50 (500 g fluticasone, 50 g salmeterol).

Approval for Advair Diskus was based on clinical trials involving more than 1,200 patients with asthma. The studies found that the combination drug improved forced expiratory volume in 1 second and increased the number of symptom-free days compared with either fluticasone or salmeterol alone. Advair Diskus was also superior to either drug alone in protecting against worsening asthma, and patients using this inhaler also required less rescue medication.

The most common side effects are similar to those of its individual components, and included upper respiratory tract infection, sore throat, viral respiratory infection, bronchitis, and headache. Advair Diskus should be used for maintenance treatment of asthma in patients at least 12 years old. The drug is not indicated for the relief of acute or potentially life-threatening episodes of asthma, nor should it be used to transfer patients from oral to inhaled corticosteroid therapy.

The approval of this combined formulation will offer an option for controlling both of the underlying components of asthma simultaneously for the 17 million Americans with asthma.

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FDA Approves Azulfidine EN-tabs as Therapy for Rheumatoid Arthritis in Children

August 23, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) has approved Azulfidine EN-tabs (sulfasalazine; manufactured by Pharmacia

Corporation) for the treatment of children 6 to 16 years old with rheumatoid arthritis. The drug is also approved for the treatment of juvenile and adult rheumatoid arthritis. This enteric-coated formulation was developed to reduce the likelihood of nausea and stomach upset.

Sulfasalazine is one of a group of disease-modifying anti-rheumatic drugs (DMARDs) that have been shown in adults to reduce or prevent joint damage and maintain joint integrity and function.

Approval for its indication in children was based on a randomized, double-blind, placebo-controlled clinical trial in which 24 weeks of Azulfidine EN-tab dosing was significantly better than placebo in reducing the number and severity of swollen joints, the number of active joints, and overall joint severity.

The most common side effects of the drug are nausea, dyspepsia, rash, immunoglobulin suppression, headache, abdominal pain, vomiting, and fever. Azulfidine EN-tabs should not be used by children with intestinal or urinary obstructions, porphyria, or hypersensitivity to sulfasalazine, sulfonamides or salicylates.

Azulfidine EN-tabs will be co-promoted in the United States with MGI Pharma, Inc., through the latter's rheumatology and oncology specialty sales organization. The new indication for this drug offers an option for the 50,000 U.S. children afflicted with rheumatoid arthritis.

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Glyburide/metformin HCl Combination Approved for Type 2 Diabetes Treatment

August 3, 2000

ST. LOUIS, (MD Consult) - The FDA has announced its approval of a new product combining glyburide and metformin HCl for initial and second-line therapy of type 2 diabetes. The new product will be marketed as Glucovance by Bristol-Myers Squibb Co., which also makes Glucophage (metformin).

Glucovance was approved for use as initial therapy for type 2 diabetes, along with diet and exercise. It is also approved as second-line therapy for patients who have inadequate glycemic control with a sulfonylurea drug or metformin alone.

The combination of drugs included in Glucovance is designed to address simultaneously the two causes of type 2 diabetes: insulin deficiency and insulin resistance. It will be available in glyburide/metformin dosing strengths of 1.25/250 mg, 2.5/500 mg, and 5/500 mg.

Lactic acidosis is a serious potential side effect, and may be fatal in about one-half of cases. Glucovance is therefore contraindicated for use in patients with renal disease. The manufacturer also recommends renal function testing before starting Glucovance in patients aged 80 years and older. Other contraindications include taking medication for heart failure, a history of liver disease, or excessive alcohol consumption. Other observed side effects include diarrhea, nausea, and hypoglycemia.

For full prescribing information on Glucovance, visit the Web site of Bristol-Myers Squibb Co.

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FDA Approves Once-Daily Concerta for ADHD

August 2, 2000

ST. LOUIS, (MD Consult) - ALZA Corporation announced today that it has received approval from the U.S. Food & Drug Administration (FDA) to market Concerta (methylphenidate HCl) extended-release tablets for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six and older.

Some other forms of medication may require two or three doses per day to achieve the desired improvement in ADHD symptoms. Concerta uses an advanced OROS ® patterned-release delivery system. The OROS ® system has been used safely for nearly 20 years in widely accepted prescription and over-the-counter medications, including medications taken by children.

"For patients taking Concerta, the need for in-school and after-school dosing will be eliminated," said Timothy E. Wilens, M.D., Associate Professor of Psychiatry, Harvard Medical School, Massachusetts General Hospital. "That's especially important for kids with after-school activities and homework. Using this once-a-day medication for ADHD can also help to eliminate the feelings of embarrassment that children may have when taking medication in the middle of the school day or during after-school activities."

According to the company press release, the efficacy of Concerta was evaluated in three double-blind, active- and placebo-controlled studies of 416 children from the ages of six through 12. The product was evaluated in multiple settings -- including community schools, laboratory schools (specialized schools used to monitor children with ADHD for treatment evaluation purposes), and at home.

Concerta qd (18, 36, or 54 mg) was compared to methylphenidate given tid (15, 30, or 45 mg total daily dose) over 12 hours and placebo in three double-blind trials in patients aged 6 to 12 years old. In these three studies, teachers and parents consistently reported a statistically significant improvement in attention and reduction in overactivity throughout the day among children taking once-daily Concerta versus placebo.

Concerta is available in 18 mg and 36 mg tablets. It should be taken in the morning, with or without breakfast. Concerta tablets must be swallowed whole with the aid of liquid and must not be chewed, divided, or crushed. In the largest controlled clinical study with patients using Concerta, the most common side effects reported were headache (14%), upper respiratory tract infection (8%), stomach ache (7%), vomiting (4%), loss of appetite (4%), sleeplessness (4%), increased cough (4%), sore throat (4%), sinusitis (3%), and dizziness (2%).

Concerta should not be taken by patients who: have significant anxiety, tension, or agitation, since Concerta may make these conditions worse; are allergic to methylphenidate or any of the other ingredients in Concerta; have glaucoma, an eye disease; have tics or Tourette's syndrome, or a family history of Tourette's syndrome; or who are taking a prescription monoamine oxidase inhibitor (MAOI).

Concerta should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence. Concerta should not be used in children under 6 years, since safety and efficacy in this age group have not been established. Concerta should not be administered to patients with preexisting severe gastrointestinal narrowing.

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FDA Grants Approval to Salix's Ulcerative Colitis Treatment Colazal

July 24, 2000

ST. LOUIS, (MD Consult) - The FDA has announced that it has approved balsalazide disodium as a new treatment for mildly to moderately active ulcerative colitis. The new product will be marketed as Colazal by Salix Pharmaceuticals, Ltd. It is already on the market in several countries in Europe and elsewhere.

Balsalazide, a sulfa-free prodrug of 5-ASA, works by delivering anti-inflammatory medication directly to the colon. According to company publicity materials, it is the first new drug approved for the treatment of ulcerative colitis in more than a decade.

Balsalazide offers a new, frontline therapy for patients with debilitating symptoms of ulcerative colitis. Approval is based on studies showing safety and effectiveness in a course of therapy lasting up to 12 weeks. Headache and abdominal pain are the most frequent side effects.

The manufacturer hopes to have balsalazide on the U.S. market early in 2001.

For full prescribing information on Colazal (balsalazide disodium), visit the Web site of the FDA. Complete prescribing information for this product is provided in Adobe's Portable Document Format (PDF). To view these documents you will need Adobe Acrobat Reader.

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Sarafem Approved for the Treatment of Premenstrual Dysphoric Disorder

July 7, 2000

ST. LOUIS, (MD Consult) - The FDA last week announced its approval of a new product containing fluoxetine hydrochloride for the treatment of premenstrual dysphoric disorder (PMDD).

The product will be marketed as Sarafem by Eli Lilly and Company. The recommended starting dose is 20 mg/d; Sarafem will be supplied in 7-day blister packs, along with patient education materials.

Women with PMDD experience severe mood and physical symptoms around the time of their menstrual period. To meet the diagnostic criteria for PMDD, the symptoms must be severe enough to interfere with the woman's regular activities and relationships, and must not represent an exacerbation of another disorder. In

addition, symptoms must occur during at least two consecutive menstrual periods.

Approval was based on clinical trials including 500 women with PMDD. Patients taking Sarafem had significant reductions in mood and physical symptoms and improvements in social functioning. These benefits were achieved in the first menstrual cycle during which the women were treated.

The safety of Sarafem was established on the basis of previous trials of fluoxetine. Adverse effects included fast talking and excitement, flu like symptoms, and irregular heartbeat.

Sarafem should not be used by patients who have taken monoamine oxidase inhibitors or thioridazine. It should be discontinued immediately if allergic symptoms develop.

The educational materials packaged with the drug will help to educate patients and physicians about the differences between PMDD and depression, and the proper treatments for each. Fluoxetine's mechanism of effectiveness against PMDD remains speculative, but may involve restoration of hormone-induced changes in the balance of the neurotransmitter serotonin.

Sarafem is the first prescription medication approved for the treatment indication of PMDD, which affects an estimated 3% to 5% of menstruating women. The manufacturer plans to have the product in pharmacies by early August.

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Antibody-targeted agent approved for treatment of relapsed acute myeloid leukemia

May 19, 2000

ST. LOUIS, (MD Consult) - The FDA's recent approval of gemtuzumab ozogamicin for injection marks two milestones: the first monoclonal antibody-based cancer chemotherapy agent and the first drug of any kind approved for the treatment of relapsed acute myeloid leukemia (AML).

The new product will be marketed as Mylotarg by Wyeth-Ayerst Laboratories, a division of American Home Products Corp.

Gemtuzumab provides a new option for patients with relapsed AML who are not suitable candidates for cytotoxic chemotherapy. Approval is specific to patients aged 60 years or older with CD33-positive AML in first relapse.

The manufacturer describes the new agent as the first in a new class of "antibody-targeted chemotherapy" agents. It combines the antitumor antibiotic calicheamicin with an antibody that binds to the CD33 glycoprotein. The CD33 antigen is found on other bone marrow cells in addition to leukemic cells; however, it is not found on pluripotent progenitor cells.

Accelerated approval was based on phase II trials including 142 patients with CD33-positive AML in first relapse. The patients achieved an overall remission rate of 26%. Gemtuzumab was designated an orphan drug in 1999.

Gemtuzumab has many potential adverse effects, including severe neutropenia and thrombocytopenia, anemia, and opportunistic infections. The rate of severe mucositis is 4%. Because the drug is antibody-targeted, it does not cause hair loss as other chemotherapy agents do.

An estimated 10,000 cases of AML occur in the United States each year, with an average patient age of 65 years. Within conventional treatment, 70% to 80% of patients will experience relapse.

The availability of gemtuzumab offers a specific new approach to achieving disease remission in these patients. The drug can be given on an outpatient basis, which is an important advantage for many patients with relapsed AML.

For prescribing information on Mylotarg, visit the Web site of the FDA. Complete prescribing information for this product is provided in Adobe's Portable Document Format (PDF). To view these documents you will need Adobe Acrobat Reader.

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FDA Approved Visudyne (verteporfin) a new Photodynamic Therapy for Age-Related Macular Degeneration

April 13, 2000

ST. LOUIS, (MD Consult) - The FDA announced on April 13, 2000, that it has approved a new injectable, laser-activated agent for the treatment of "wet" age-related macular degeneration (AMD). AMD is the most common cause of blindness in older adults. The new product, called verteporfin, will be marketed as Visudyne by CIBA Vision. It was developed by QLT Phototherapeutics, a Canadian firm.

Verteporfin provides a new approach to slowing visual loss in patients with wet AMD, associated with classic subfoveal choroidal neovascularization (CNV). Wet AMD is the less common but more severe type of AMD.

Verteporfin treatment can be carried out in the physician's office. The drug is injected intravenously into the patient's arm. Five minutes later, it is activated by shining low-level, nonthermal laser light into the eye. The agent is activated only in the abnormal vessels and tissues. This interrupts the process of CNV, thus helping to reduce or stabilize visual loss. Normal areas of the eye are undamaged.

Each year, an estimated 200,000 Americans suffer visual loss as a result of wet AMD. About 10% to 15% of cases of AMD are of this type--the rest are "dry," associated with drusen deposits. However, the wet form is responsible for about 90% of severe visual loss resulting from AMD.

Laser-activated verteporfin is the first drug ever approved for the treatment of wet AMD. According to CIBA Vision, it will be available immediately.

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New Drug Actonel (risedronate sodium tablets) and Activella for the new Indication of the Prevention of Osteoporosis

April 19, 2000

ST. LOUIS, (MD Consult) - The FDA has cleared for marketing the new drug Actonel for the treatment of osteoporosis and approved a new indication for Pharmacia & Upjohn's Activella.

Actonel (risedronate sodium tablets) is indicated in the treatment and prevention of postmenopausal osteoporosis and glucocorticoid-induced osteoporosis. Procter & Gamble, the inventor of Actonel, and Aventis Pharmaceuticals will market the drug collaboratively.

Actonel 5 mg is the first osteoporosis therapy to consistently demonstrate a reduction in vertebral fractures in just one year of treatment. Additionally, Actonel is the only therapy to show this one-year vertebral fracture benefit in patients with glucocorticoid-induced osteoporosis as well.

Actonel should not be used in patients with low blood calcium or in patients with severe kidney disease.

The FDA also approved Pharmacia & Upjohn's Activella for the new indication of the prevention of osteoporosis. Activella is a continuous-combined once daily tablet combining estrogen (1 mg estradiol) and progestin (0.5 mg norethindrone acetate). It was previously approved by the FDA for the treatment of moderate to severe vasomotor symptoms associated with menopause and for vulvar and vaginal atrophy associated with menopause.

Common side effects may include breast tenderness/pain, upper respiratory complaints, headache and postmenopausal bleeding.

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FDA Approved Zyvox (linezolid) for the Treatment of Patients with Infections Caused by Gram-Positive Bacteria.

April 19, 2000

ST. LOUIS, (MD Consult) - The U.S. Food and Drug Administration (FDA) approved ZYVOX (linezolid) for the treatment of patients with infections caused by Gram-positive bacteria. With IV and oral formulations, Zyvox comes from the first completely new class of antibiotics to reach hospitals in 35 years, the oxazolidinones.

Zyvox is indicated for adults in the treatment of:

- nosocomial pneumonia
- community-acquired pneumonia
- complicated and uncomplicated skin and skin structure infections
- vancomycin-resistant Enterococcus (VRE) infections
- complicated skin infections caused by methicillin-resistant Staphylococcus aureus
- nosocomial pneumonia caused by methicillin-resistant Staphylococcus aureus
- concurrent bacteremia associated with vancomycin-resistant Enterococcus

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- concurrent bacteremia associated with community-acquired pneumonia caused by penicillin-susceptible Streptococcus pneumoniae.

The most common events for patients treated with ZYVOX were diarrhea, headache, nausea and vomiting. Events were usually mild to moderate in intensity and limited in duration. Certain patients should have periodic monitoring of their blood platelet levels while taking ZYVOX.

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FDA Approved for Marketing Mobic ® (meloxicam) Tablets for the Treatment of Osteoarthritis.

April 19, 2000

ST. LOUIS, (MD Consult) - The US Food and Drug Administration has approved for marketing MOBIC ® (meloxicam) tablets for the treatment of osteoarthritis.

MOBIC tablets will be marketed in the United States jointly by Boehringer Ingelheim Pharmaceuticals, Inc. and Abbott Laboratories.

In the United States, MOBIC tablets are indicated as a once-daily medication for relief of the signs and symptoms of osteoarthritis. MOBIC is the third new non-steroidal anti-inflammatory drug (NSAID) introduced to the market in the past two years, following CELEBREX ® and VIOXX ®.

Patients who have a known allergy to meloxicam, aspirin or other traditional NSAIDs should not use MOBIC tablets, nor should women who are, or may be, pregnant. Although use of MOBIC tablets shows good gastrointestinal tolerability, patients and physicians should remain alert to the earliest signs and symptoms of gastrointestinal bleeding.

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Zonegran (zonisamide) Approved for Partial Seizures

March 29, 2000

ST. LOUIS, (MD Consult) - The FDA has granted approval to zonisamide, a new antiseizure drug that effectively reduces the frequency of partial seizures in adult patients when added to other antiepileptic therapies. The drug will be marketed as Zonegran in the United States and Europe by Elan Corporation.

Zonisamide will be useful in the treatment of partial seizures in epileptic patients that are not completely controlled by single-drug regimens. Approval was based on three randomized, placebo-controlled trials including 499 patients who had refractory partial-onset seizures, with or without secondary generalization. Added to other antiepileptic drugs, zonisamide significantly reduced the frequency of partial seizures, compared with placebo.

The starting dose of zonisamide is 100 mg/d, increasing as necessary to achieve a response. Its safety and effectiveness have not been established in children under

age 16.

The most frequent side effects are somnolence, anorexia, dizziness, headache, nausea, and agitation/irritability. It is contraindicated for use in patients with hypersensitivity to sulfonamides. Other potential adverse effects include serious skin rashes and kidney stones.

For full prescribing information on Zonegran, visit the Web site of the FDA. Complete prescribing information for this product is provided in Adobe's Portable Document Format (PDF). To view these documents you will need Adobe Acrobat Reader.

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ReFacto (antihemophilic factor recombinant) an Albumin-Free Recombinant Factor VIII Approved for Treatment of Hemophilia A

March 7, 2000

ST. LOUIS, (MD Consult) - The FDA announced on March 7, 2000, that it has approved a new recombinant factor VIII--the first such product to be manufactured without the use of serum human albumin--for prophylactic use in patients with hemophilia A.

The new product--generic name antihemophilic factor (recombinant)--will be marketed as ReFacto by the Genetics Institute of Wyeth-Ayerst Laboratories, a division of American Home Products Corp.

ReFacto provides hemophilic patients with a new alternative for control and prevention of bleeding episodes, including prophylaxis for surgical procedures. It can also be used on a short-term basis to reduce the rate of spontaneous bleeding episodes.

Because no human albumin is used in the final step of formulation, ReFacto reduces the risk of viral transmission in patients with hemophilia A. No cases of viral transmission have been reported in over 60,000 ReFacto infusions given to date. As for previous recombinant factor VIII products, albumin is used during the cell culture phase.

ReFacto has been studied in a total of 218 patients with hemophilia A, including 101 previously untreated patients. Approval trials showed that the new product was effective in preventing and controlling bleeding episodes.

Side effects of ReFacto include headache, fever, nausea, and allergic reactions, as for other protein products administered intravenously.

The new product represents a new advancement in safe, effective treatment of hemophilia A. It is estimated that about 17,000 Americans are affected by this inherited bleeding disorder.

Genetics Institute has played a major role in developing new treatments for hemophilia, including a major research partnership with the National Hemophilia Foundation.

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Betapace AF (sotalol hydrochloride)

February 24, 2000

ST. LOUIS, (MD Consult) - Berlex Laboratories, Inc. announced on February 24, 2000, that the Food & Drug Administration (FDA) approved Betapace AF (sotalol hydrochloride) for the maintenance of normal sinus rhythm in patients with symptomatic atrial fibrillation and atrial flutter (AFIB/AFL) who are currently in sinus rhythm. Administered orally, Betapace AF is an antiarrhythmic drug with Class II (adrenoreceptor blocking) and Class III (cardiac action potential duration prolongation) properties.

Because Betapace AF can cause life-threatening ventricular arrhythmias, Betapace AF should be reserved for patients in whom AFIB/AFL is highly symptomatic. To minimize the risk of induced arrhythmia, patients initiated or re-initiated on Betapace AF should be placed for a minimum of three days in a facility that can provide cardiac resuscitation, continuous electrocardiographic monitoring and calculations of creatinine clearance.

Sotalol is also indicated for treatment of documented life-threatening ventricular arrhythmias and is marketed under the brand name Betapace. Betapace should not be substituted for Betapace AF due to significant differences in the product labeling.

Like other antiarrhythmic drugs Betapace AF can provoke serious ventricular rhythm disturbances in some patients and like other drugs with beta-blocking activity, Betapace AF can worsen congestive heart failure.

Proarrhythmias may be associated with predisposing risk factors (e.g., hypokalemia, hypomagnesemia, bradycardia, female gender, prolongation of the QTc interval to >500ms and a history of cardiomegaly, congestive heart failure or sustained VT/VF). Adverse events that are clearly related to Betapace AF are those which are typical of its Class II (beta-blocking) and Class III (cardiac action potential duration prolongation) effects.

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Prevnar (pneumococcal vaccine) Approved for Children Under 2

February 17, 2000

ST. LOUIS, (MD Consult) - On February 17, 2000, the FDA granted approval to a new vaccine that prevents pneumococcal bacteremia and meningitis in children under 2 years old--the first pneumococcal vaccine approved for use in this high-risk age group.

The new vaccine--pneumococcal 7-valent conjugate vaccine--is 90% to 100% effective in preventing disease caused by various strains of *Streptococcus pneumoniae*, according to the studies on which approval was based. The vaccine will be marketed by Wyeth Lederle Vaccines as Prevnar.

A controlled, double-blind trial including approximately 38,000 children was performed at Northern California Kaiser Permanent. Among children receiving Prevnar, there were no cases of invasive pneumococcal disease caused by the strains included in the 7-valent vaccine. Furthermore, the vaccine was 90% effective in preventing pneumococcal disease caused by other strains.

Most side effects were mild, including injection site reactions, irritability, and fever.

Children received four doses of the vaccine, at 2, 4, 6, and 12 to 15 months of age. Pneumococcal 7-valent conjugate vaccine is not indicated for use in adults, nor is it considered a substitute for pneumococcal polysaccharide vaccines already approved for use in high-risk children over 2.

Pneumococcal bacteremia, meningitis, and other invasive pneumococcal diseases are an important cause of morbidity and mortality in children less than 5 years old. Since the introduction of *Haemophilus influenzae* type b conjugate vaccine, *S. pneumoniae* has been one of the major causes of bacterial meningitis.

The new product is the first multivalent conjugate pneumococcal vaccine approved for use in children under age 2--the group at highest risk of infection. It is hoped that by preventing invasive pneumococcal disease before it occurs, pneumococcal 7-valent conjugate vaccine will avoid consequences such as brain damage, hearing loss, and death. The vaccine's effects on the rate of ear infections--another major *Streptococcus*-associated health problem of early childhood--remain to be determined.

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Lotronex (alosetron)

February 10, 2000

ST. LOUIS, (MD Consult) - A new alternative for the treatment of irritable bowel syndrome (IBS) is on the way, and it may be just the first of a new generation of specific agents for this common problem.

The new drug--called alosetron hydrochloride, to be marketed as Lotronex--was approved last week by the U.S. Food and Drug Administration for use in selected female patients with IBS.

A potent, selective 5-HT3 antagonist, alosetron has proven effective in the treatment of women with IBS whose major symptom is diarrhea. In two large, phase III clinical trials, alosetron was superior to placebo in reducing several key symptoms of IBS, including pain and discomfort and stool frequency and urgency.

The benefits persist through 12 weeks of treatment; symptoms return when the medication is discontinued. The effects of alosetron have not been studied beyond 12 weeks, and have not been studied in men.

Constipation is the major side effect of alosetron. It is not indicated for use in patients who already have constipation, or those in whom constipation is the main feature of IBS.

Alosetron will be available in 1 mg tablets, with a recommended dosing of one tablet twice daily. It should be available for prescription by mid-March.

The new medication was developed by GlaxoWellcome. According to company publicity materials, IBS affects about 1 in 5 adults, and is about three times more common in women than men. Alosetron's mechanism of action is not entirely clear, but may involve blockade of serotonin's action at 5-HT3 sites in the enteric nervous system.

The studies on which approval was based suggest that alosetron will address multiple IBS symptoms, unlike currently available medications. It is expected to be the first of a new generation of medications specifically designed for the treatment of IBS.

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Protonix (pantoprazole sodium)

February 2, 2000

ST. LOUIS, (MD Consult) - American Home Products Corporation announced on February 2, 2000, that Protonix (pantoprazole sodium) Delayed-Release tablets were approved by the U.S. Food and Drug Administration (FDA) for the short-term (up to sixteen weeks) treatment in the healing and symptomatic relief of erosive esophagitis (EE). Protonix is the newest drug in the drug class known as proton pump inhibitors (PPI). Protonix will be launched in the second quarter 2000 pending the successful completion of an ongoing mouse safety study and FDA approval of the IV form.

More than 40 percent of adults - nearly 60 million Americans - experience symptoms of GERD (typically a burning pain behind the breastbone) two or more times per week. If left untreated or uncontrolled, esophageal damage caused by GERD may lead to even more serious complications, including stricture, hemorrhage, a precancerous condition known as Barrett's esophagus, and esophageal cancer.

In clinical trials, the most frequently reported side effects in patients taking pantoprazole - headache, diarrhea, and flatulence - occurred in about the same rates as placebo. Pregnant women should use the compound only if clearly needed, and physicians should evaluate continuing drug use in nursing mothers.

Proton pump inhibitors are one of the most widely prescribed classes of medications in the United States. The first proton pump inhibitor was launched in the U.S. in 1989. Pantoprazole is currently marketed in 60 countries.

For full prescribing information on Protonix (Pantoprazole Sodium), visit the Web site of the FDA. Complete prescribing information for this product is provided in Adobe's Portable Document Format (PDF). To view these documents you will need Adobe Acrobat Reader.

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Trileptal (oxcarbazepine)

January 17, 2000

ST. LOUIS, (MD Consult) - Novartis Pharmaceuticals Corporation announced on January 17, 2000, that the U.S. Food and Drug Administration (FDA) had granted marketing clearance for Trileptal (oxcarbazepine) tablets. The medication is indicated for the treatment of partial seizures as monotherapy in adults or adjunctive therapy in adults and children as young as four years of age.

Four well-controlled multicenter trials were conducted in the U.S. to demonstrate the safety and efficacy of Trileptal as monotherapy. In these trials, Trileptal demonstrated efficacy (compared to placebo or low doses of Trileptal) in those patients poorly controlled on their current therapies and in newly diagnosed patients.

- In a 10-day trial of epilepsy surgery candidates who were previously unresponsive to other antiepileptic drugs (AEDs), 25% of patients given Trileptal remained seizure free compared to 2% of placebo patients.
- In other controlled monotherapy trials of newly diagnosed patients, 57-61% of those on Trileptal were seizure free during 48 weeks of study.

Use of Trileptal as adjunctive therapy was evaluated in two multicenter, randomized, double-blind, placebo-controlled trials. Trileptal use resulted in fewer seizures when added to a prior drug regimen of one or more other AEDs:

- In adult patients, Trileptal significantly reduced the frequency of seizures as compared to placebo.
- Trileptal demonstrated efficacy at the starting dose (600 mg/day).
- In pediatric patients, Trileptal significantly reduced the frequency of seizures as compared to placebo.

In clinical trials, there was no significant difference between Trileptal and placebo in side effects that especially concern people with epilepsy, such as, coarsening of the facial features; gingival hyperplasia (swelling of the gums); hirsutism (abnormal hair growth); difficulty concentrating; memory problems; abnormal coordination; weight gain; tremor; hair loss or rash.

The side effects associated with Trileptal in monotherapy (> 5%) were dizziness, nausea, headache, diarrhea, vomiting, upper respiratory tract infection, constipation, dyspepsia, ataxia and nervousness. A less commonly seen side effect (2.5% in controlled clinical trials) was hyponatremia (low serum sodium levels), which was usually asymptomatic and did not usually require dose adjustments. Trileptal should not be used in patients with a known hypersensitivity to oxcarbazepine or to any of its components.

For full prescribing information on Trileptal (oxcarbazepine), visit the Web site of the FDA. Complete prescribing information for this product is provided in Adobe's Portable Document Format (PDF). To view these documents you will need Adobe Acrobat Reader.

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